

ATTACHMENT - REMARKS

Claims 1, 3, 4, 8 and 10-15 are pending in the present application. By this Amendment, Applicants have amended claim 12 and canceled claim 16. Applicants respectfully submit that the present application is in condition for allowance based on the discussion which follows.

As an initial comment, Applicants gratefully appreciate the Examiner conducting a telephonic interview with their representative, Mr. Stephen Weyer, on June 15, 2010. In accordance with that interview, Applicants have amended the claims and present the following remarks.

Claims 11, 12, 14 and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Howard (U.S. Patent No. 4,335,116) (hereinafter "Howard"). In maintaining the rejection, it was alleged that Howard discloses a trace element solution having various ranges of metal concentrations which, if the upper end of the ranges were combined in a single solution, that solution would have a 72 mg/ml trace metal concentration.

Contrary to the obviousness-type rejection, Applicants respectfully submit that Howard fails to be an anticipatory reference of claims 11, 12 and 14, as Howard fails to enable one of ordinary skill in the art to practice the claimed invention with regard to a trace element solution comprising a metal concentration of 60 mg/ml. Applicants respectfully note that, in order for a prior art reference to be an anticipatory reference, the prior art must allow one of ordinary skill in the art to practice the claimed invention without undue experimentation. *Elan Pharma., Inc. v. Mayo Found.*, 64 U.S.P.Q.2d 1292 (Fed. Cir. 2002). Factors to be considered in determining whether undue

experimentation is required are provided in *In re Wands*, 858 F.2d 731, 737; 8 U.S.P.Q. 1400, 1404 (Fed. Cir. 1988) and include the state of the art, level of predictability in the art, existence of working examples, and the amount of direction by the author/inventor of the prior art (hereinafter collectively referred to as the "*Wands'* factors") (*Elan Pharma.*).

Applicants respectfully submit that all of the aforementioned *Wands'* factors weigh against finding that one of ordinary skill in the art would have been able to practice the claimed invention, i.e. produce a trace elements solution having a metal concentration comprising 60 mg/ml, without undue experimentation. The state of the art at the time of Howard did not include knowledge of how to produce a trace metal solution having a metal concentration comprising 60 mg/ml. See the previously submitted Declaration of William Alfred Smith under 37 C.F.R. § 1.132 (hereinafter "*Smith Dec.*") (Smith Dec., ¶¶ 7-10). Further, the method disclosed in Howard would not have allowed one of ordinary skill in the art to produce a trace element solution having a metal concentration comprising 60 mg/ml, let alone 72 mg/ml (Smith Dec., ¶¶ 4-7 and 10). In fact, all examples in Howard are directed to a substantially smaller concentration than 60 mg/ml (Smith Dec., ¶¶ 4-7). For example, Howard "Example 1" discloses a 13.5 mg/ml trace element solution and "Example 2" discloses a 2.375 mg/ml trace element solution. See, e.g., Remarks to the Amendment filed September 1, 2009, page 3, for a further discussion on the specific examples and respective concentrations in Howard. Accordingly, the examples in Howard establish the *Wands'* factor of a lack of examples to enable one of ordinary skill in the art to practice the present invention

with regard to a metal concentration comprising 60 mg/ml, i.e. a metal concentration between 4.4 and 25 times higher than the metal concentration enabled by Howard.

Furthermore, the method disclosed by Howard for producing its trace metal concentration is insufficient to allow one to produce a metal concentration of 72 mg/ml, let alone 60 mg/ml, as claimed (Smith Dec., ¶ 7). The reason the Howard method would be insufficient for producing the higher concentrations required include the fact that Howard discloses a method of producing individual trace metal solutions which are combined together to form a single trace element solution comprising all of its trace elements. Thus, Howard discloses a batch method for producing a combined trace metal solution. Further, Howard uses tetrasodium EDTA, which has a relatively lower complexing power than other forms of EDTA (Smith Dec., ¶ 9). Accordingly, the tetrasodium EDTA used and the batch method disclosed in Howard establish a lack of direction by the inventor to allow one of ordinary skill in the art to practice higher concentrations of a metal in the trace element solution, in accordance with the *Wands*' factors.

Furthermore, the *Wands*' factor regarding the state of the art weighs against finding enablement in Howard to produce the claimed solution. At the time of Howard, the state of the art did not include knowledge of how to produce a trace element solution having the claimed concentrations. Howard fails to disclose any method which produces a trace metal solution having a trace metal concentration which in any way approaches the high metal concentration claimed. Moreover, Howard is completely silent with regard to providing any direction on how to produce a trace metal solution having the claimed concentrations. It is respectfully noted that, in contrast to Howard,

the present specification fully enables one of ordinary skill in the art to produce the claimed trace metal solution, in that the present invention provides actual examples and discloses a method completely different from Howard which allows one of ordinary skill in the art to produce the claimed solution having a metal concentration of 60 mg/ml.


In view of the foregoing, Applicants respectfully submit that Howard fails to be an anticipatory reference or in any way make obvious the claimed trace metal solution having a metal concentration comprising 60 mg/ml, as Howard fails to enable one of ordinary skill in the art to practice the invention as claimed. Therefore, in accordance with the holding in *Elan Pharma.*, Howard is not an anticipatory reference with regard to the claimed trace element solution. Accordingly, Applicants respectfully request that the rejection to claims 11, 12 and 14 under 35 U.S.C. § 103(a) as being unpatentable over Howard be withdrawn.

Applicants respectfully submit that the present application is in condition for allowance. Should the Examiner come to a contrary conclusion, the Examiner is invited to call the undersigned at the telephone number listed below.

Respectfully submitted,

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Signed By
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